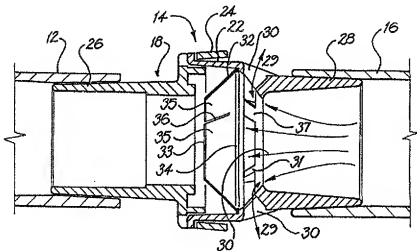




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(21) International Application Number: PCT/AU99/01169 (22) International Filing Date: 23 December 1999 (23.12.99) (30) Priority Data: PP 7945 24 December 1998 (24.12.98) AU (71) Applicant (for all designated States except US): RESMED LIMITED [AU/AU]; Legal Department, 97 Waterloo Road, North Ryde, NSW 2113 (AU). (72) Inventors; and (75) Inventors/Applicants (for US only): WALKER, Adrienne, Mary, Claire [AU/AU]; Unit 5, No. 38, Carlton Crescent, Summer Hill, NSW 2113 (AU); CRUMBLIN, Geoffrey [AU/AU]; 17 Benwerrin Avenue, Baulkham Hills, NSW 2153 (AU); SMART, Gregory, Scott [AU/AU]; 3/19 Bishops Avenue, Randwick, NSW 2031 (AU); GUNARATNAM, Michael, Kassipillai [AU/AU]; 3 Keiley Street, Marsfield, NSW 2122 (AU). (74) Agent: SPRUSON & FERGUSON; G.P.O. Box 3898, Sydney, NSW 2001 (AU).		(81) Designated States: AE, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG). Published With international search report.

(54) Title: AN ANTI-ASPHYXIA VALVE



(57) Abstract

An anti-asphyxia valve (14) adapted to, in use, be disposed between a patient (21) and means (10) to deliver a breathable gas to the patient (20). The valve (14) comprises a housing (18, 20) having an interior, at least one port (30) to provide fluid communication between the housing interior and atmosphere and a flap means (32) comprising a first portion (34) adapted for mounting to the housing (18, 20) and a second portion (35) adapted to flex. The second portion (35) flexes between a first biased open position allowing gas to pass from the housing interior through the port(s) (30) to atmosphere when the difference in gas pressure in the housing interior and atmosphere is below a predetermined operating threshold and a second forced closed position substantially occluding the port(s) (30) when the difference in gas pressure between the housing interior and atmosphere is substantially equal to or above the operating threshold.

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## AN ANTI-ASPHYXIA VALVE

## FIELD OF THE INVENTION

The present invention relates to an anti-asphyxia valve.

- The valve has been developed primarily for use between a patient and a means to deliver a breathable gas to the patient, such as is used in the Continuous Positive Airway Pressure (CPAP) treatment of Obstructive Sleep Apnea (OSA) syndrome, and will be described hereinafter with reference to this application. The valve is also suitable for use in other gas delivery systems, such as those used in assisted respiration and Non-Invasive Positive Pressure Ventilation (NIPPV).

## 10 BACKGROUND OF THE INVENTION

- Nasal masks are currently employed for various purposes, including the delivery of oxygen to persons who suffer from lung disease or who are exposed to rarefied atmospheres, for administering anaesthetic gases and for delivering pressurised air to persons who suffer from sleep disordered breathing conditions, such as OSA, or for the delivery of non-invasive ventilation. The mask cushions are usually moulded from a relatively soft, resilient, elastic material and they are shaped during manufacture to match the facial contours of an average intended wearer. However, a problem with the known types of masks is that, because individuals vary so much from the average, the masks must be forced against their inherent resiliency to deform and so adapt to the shapes of the users in order to avoid gas leakage. This requires that the masks be secured firmly by retaining straps or harnesses in order to prevent air leakage.

- Flow generators are typically utilised to deliver a breathable gas (ie. air) to a patient wearing the mask. In CPAP treatment, gas is delivered to the patient's airways at about 2-30 cm H<sub>2</sub>O above atmospheric pressure. The flow generator is generally connected to flexible tubing which is secured to the mask worn by the patient. If the flow generator's operation is interrupted as a result of a power outage or other mechanical or electrical failure, there may be a significant build up of carbon dioxide in the mask as the patient's exhaled air is not washed out of outlet vents which are usually contained in the mask. This may present a health problem to the patient.

- There have been numerous patents which have addressed some sort of safety valve for gas or air delivery masks. An example of such a patent is U.S. Patent No. 5,438,981. This patent discloses a counter balanced, rigid valve element which depending on the gas flow, either covers an opening to the ambient air or covers the gas flow airway such that the air or breathing gas is forced out into the ambient air opening. However, this system suffers from being a fairly complicated and expensive system whose correct operation relies on a counter balanced moving part moving relative to its housing. Further, if any condensation from the air gets on or around the

balanced valve element, the operation of this valve element can be compromised. This valve is also difficult to clean.

Applicant's international PCT patent application No. PCT/AU97/00849 discloses a valve having a single valve element. However, whilst being simpler than  
5 preceding valves of this type, the valve shown in PCT/AU97/00849 still relies on the use of a rigid valve element moving relative to its housing and biased by magnets.

It is an object of the present invention to provide an improved valve of simpler construction than those prior art valves discussed above.

#### SUMMARY OF THE INVENTION

Accordingly, in a first aspect, the present invention provides an anti-asphyxia  
10 valve adapted to, in use, be disposed between a patient and means to deliver a breathable gas to the patient, the valve comprising a housing having an interior, at least one port to provide fluid communication between the housing interior and atmosphere  
15 and a flap means comprising a first portion adapted for mounting to the housing and a second portion adapted to flex between a first biased open position allowing gas to pass from the housing interior through the port(s) to atmosphere when the difference in gas pressure in the housing interior and atmosphere is below a predetermined operating threshold and a second forced closed position substantially occluding the port(s) when  
20 the difference in gas pressure between the housing interior and atmosphere is substantially equal to or above the operating threshold.

The operating threshold can be altered to suit particular applications. For example, a valve suitable for use in adult ventilatory assist therapy has an operating threshold of about 2 cm H<sub>2</sub>O.

The second portion preferably completely occludes the ports in the closed  
25 position.

Preferably, the housing is comprised of two housing parts which are releasably engageable with one another. In an embodiment, the housing parts engage by way of bayonet style fittings.

Desirably, the housing includes a gas inlet in the form of a first substantially  
30 frusto-conical portion adapted to frictionally engage a flexible conduit in fluid communication with the means to deliver a breathable gas to the patient and a gas outlet in the form of a second substantially frusto-conical portion adapted to engage a mask or a flexible or rigid conduit in fluid communication with the mask. The frusto-conical portions preferably taper from a smaller distal end to a larger proximal end relative to  
35 the housing of the inlet valve.

Desirably also, one of the gas inlet or outlet includes a snap-engageable and detachable swivel portion adapted to engage the mask or flexible conduit. In a preferred embodiment, the inlet and outlet are respectively provided on one of the two housing parts.

In an embodiment, the housing includes a plurality of ports spaced about the periphery thereof and the second portion of the flap means includes a like plurality of flaps. In one preferred form, the housing includes six ports (three pairs of ports) and the second portion of the flap means includes three flaps each adapted to close adjacent pairs of the ports. In another embodiment, the second portion of the flap means is a single flap which is adapted to occlude all the port(s) in the second position. The single flap can also include perforations, ribs, pleats or folds or the like.

In one form, the first and second portions are integrally formed. In another form, the first and second portions are initially formed from separate components that are later attached to each other.

The first portion preferably includes a rim adapted to assist in mounting the flap means to the housing. In an embodiment, the rim is an external rim of rectangular cross section which is adapted to engage an internal recess of substantially like cross-section in the housing.

The first portion can also include a cylindrical portion between the rim and the second portion.

The rim and/or the cylindrical portion can also be tapered.

The second portion of the flap means preferably terminates in an internal orifice. In a preferred embodiment, the orifice can include a one-way valve adapted to only allow gas flow through the orifice in a direction towards the patient.

In one preferred form, the flap means is substantially round in cross-section. In other forms, the cross-section of the flap means is full or part elliptical or rectangular or other out-of-round shapes.

The housing is preferably manufactured from plastics material, for example polycarbonate. The flap assembly is preferably manufactured from a flexible elastomeric material such as a silicone rubber.

In another embodiment, the valve is integral with a mask.

In a further embodiment, the housing is of unitary construction.

#### BRIEF DESCRIPTION OF THE DRAWINGS

Preferred embodiments of the invention will now be described, by way of example only, with reference to the accompanying drawings in which:

Fig. 1 is a general schematic drawing of a system comprising a flow generator being connected to a valve and mask via tubing in which the mask is connected to a patient;

Fig. 2 is a side view of a valve of the present invention;

Fig. 3A is a cross sectional view of Fig. 2 in which the flow generator is not operating;

Fig. 3B is a cross sectional view of Fig. 2 in which the flow generator is operating and generating a pressure differential below the operating threshold;

Fig. 4 is a cross sectional view of the valve of Fig. 2 in which the flow generator is operating and generating a pressure differential above the operating threshold;

Fig. 5 is a perspective view of an alternative embodiment of the present invention wherein the valve is attached to a mask having a CO<sub>2</sub> gas washout vent;

Fig. 6 is a cross sectional view of a further embodiment of the present invention wherein the valve has a unitary housing;

Fig. 7 is a cross sectional view of a yet further embodiment of the present invention wherein the valve includes a swivel conduit connector;

Fig. 8 is a perspective view of another embodiment of the present invention wherein the valve is integral with a mask;

Fig. 9 is a cross sectional view of an embodiment of a flap means;

Fig. 10 is a cross sectional view of another embodiment of a flap means;

Fig. 11 is a cross sectional view of yet another embodiment of a flap means;

Fig. 12 is a perspective view of a further embodiment of a flap means;

Fig. 13 is a perspective view of a further embodiment of a flap means;

Fig. 14 is a perspective view of a further embodiment of a flap means;

Fig. 15 is a perspective view of a further embodiment of a flap means;

Fig. 16 is a perspective view of the flap means shown in Fig. 11;

Fig. 17 is a perspective view of a further embodiment of a flap means;

Fig. 18 is a half-cutaway view of the flap means shown in Fig. 17;

Fig. 19 is a first sectional view of the flap means of Fig. 17 along the line 19, 20-19, 20;

Fig. 20 is a second sectional view of the flap means of Fig. 17 along the line 19, 20-19, 20;

Fig. 21 is a sectional view of the flap means of Fig. 17 along the line 21-21;

Fig. 22 is a perspective view of a further embodiment of a flap means;

Fig. 23 is a cross sectional side view of the flap means of Fig. 22 in the open position; and

Fig. 24 is a cross sectional side view of the flap means of Fig. 22 in the closed position.

#### DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention can be used for any air or oxygen delivery system wherein there is some type of flow generator connected to a tube or airflow conduit which is thereafter secured to a mask which is secured to a patient. The gas being transmitted can be any type of breathable or therapeutic gas. The general schematic of this is shown in Fig. 1 wherein there is a flow generator 10 having a flexible air flow conduit 12 secured to an embodiment of a valve 14 of the present invention which is thereafter connected to a nasal mask 16 of a patient 21. The mask 16 shown includes a

mask cushion 17 and a CO<sub>2</sub> gas washout vent 19 and is just one example of numerous types of patient interface.

The location of the valve 14 shown in Fig. 1 is just one example of numerous possible locations. The valve 14 could be connected to the mask 16 as shown in Figs. 1 and 5, or it could be an integral part of the mask 16, as shown in Fig. 8. There could also be two or more valves located on a single system. It is preferred to put the valve 14 as close to the mask 16 as possible, or to make it part of the mask 16.

The flow generator 10 produces a flow of breathable gas, typically air, and can be an electric blower, a controlled bottled gas system, a ventilator, or any other type of device that delivers breathable, therapeutic or anaesthetic gas.

The valve 14 shown in Figs. 1 to 4 is comprised of two housing parts 18 and 20 which may be locked together by way of respective male and female bayonet fittings 22 and 24. The housing part 18 includes an inlet in the form of frusto-conical portion 26. The housing part 20 includes an outlet in the form of frusto-conical portion 28. The portions 26 and 28 allow push-on assembly and frictional engagement with the gas supply conduit 12 and the mask housing 16 respectively. The housing part 20 includes six peripherally arranged ports 30 each separated by one of six connecting members 31. A flexible flap means 32 of generally round cross-section is formed from a silicone rubber and has a central orifice 33. The flap means 32 includes a first portion in the form of outer rim 34. The flap means 32 is glued, clamped or otherwise attached or mounted to the second housing part 20 at the outer rim 34. The flap means 32 includes a second portion in the form of flexible flaps 35.

As shown in Fig. 3A, when the difference in the gas pressure between the housing interior and atmosphere is below a predetermined operating threshold of, for example 2 cm H<sub>2</sub>O, the flaps 35 are in a relaxed state and inherently biased to an "open" position allowing gas flow from the interior of the housing through the ports 30 and to atmosphere. Accordingly, if the supply of breathable gas falls below the threshold or ceases, the patient 21 is still able to inhale air through the open ports 30 and exhale carbon dioxide out through the open ports 30, as indicated by arrows 29.

When the breathable gas supply commences or resumes and the difference in the gas pressure between the housing interior and atmosphere builds up to equal or above 2 cm H<sub>2</sub>O the flaps 35 move to a "closed" position occluding the ports 30 shown in Fig. 4. Thereafter the flaps 35 are maintained closed by the gas pressure in the housing interior being above the predetermined operating threshold. In this closed position all the gas supplied from the flow generator 10 can pass through the orifice 33 of the flap assembly 32 to be delivered to the mask 16 of the patient 21, as indicated by arrows 39.

In the embodiment shown in Figs. 1 to 4, the flap means 32 has three of the flaps 35 which each subtend an angle of approximately 120°. The three flaps 35 are

each separated by slits 36 (only one of three slits 36 shown). The slits 36 allows the flaps 35 to flex between the open and closed positions, as shown in Fig. 3A and Fig. 4 respectively, without crinkling or binding. Every second one of the six connecting members 31 includes a flange 37 which abuts adjacent outer edges (adjacent the slits 36) of each of the flaps 35 in the closed position to assist in sealing the ports 30.

The flap means 32 is preferably manufactured by moulding of a single silicone rubber component in the shape shown in Fig. 3A (ie. the open position). The flaps 35 are preferably 0.15 mm thick. The thickness of the flaps are adjusted to suit their application and, in particular, the pressure of the operating threshold. If too flimsy, the flaps will distend or crumple across the ports 30 and may not move to return from the closed position at the correct pressure. If too stiff, the flaps will not move to the closed position at the correct pressure.

Testing of a prototype of the valve 14 shown in Figs. 1 to 4 was conducted with a flow generator connected to the inlet cylindrical portion 26 via an air flow conduit. A mask was connected to the valve 14 at the outlet cylindrical portion 28. The mask cushion seals the mask interior relative to the wearer's face such that the only gas flow from the mask 16 to atmosphere is through the mask gas washout vent.

With this arrangement the flap assembly 32 closed the ports 30 at an approximately 2 cm H<sub>2</sub>O pressure difference (operating threshold) between the interior of the valve 14 and atmosphere.

The inherent resilience of the silicone rubber flaps 35 re-opened the ports 30 when the pressure difference (operating threshold) between the interior of the valve 14 and atmosphere fell below approximately 2 cm H<sub>2</sub>O.

Fig. 3B shows the flap assembly 32 in the open position when the flow generator is operating but the pressure difference between the valve interior and atmosphere is below the operating threshold. Under these conditions, some of the supplied gas passes through the ports 30 and the remainder passes through the valve outlet 28 to the mask, as indicated by arrows 27 and 39 respectively.

As the flow through the valve outlet 28 is thus less than the supplied flow through the valve inlet 26, a pressure differential is created between the downstream side of the flaps 35 (that side adjacent the valve outlet 28) and the upstream side of the flaps 35 (that side adjacent the valve inlet 26) which forces the flaps 35 to deform against their inherent resilience towards the ports 30 and, ultimately, to the closed position shown in Fig. 4.

When in the closed position shown in Fig. 4, there is no gas flow through the ports 30. Under these conditions, a pressure differential between the valve interior and atmosphere above the operating threshold will maintain the flaps 35 in the closed position.



The inherent resilience of the flaps 35 moves the flaps 35 away from the ports 30 and towards the open position when the pressure difference between the valve interior and atmosphere falls below the operating threshold.

Fig. 5 illustrates another embodiment in which the valve 14 is attached to another type of mask 16 that includes a CO<sub>2</sub> gas washout vent 38.

Fig. 6 illustrates an embodiment of the valve 14 having a unitary housing 40.

Fig. 7 illustrates another embodiment of the valve 14 having a unitary housing 40 and a swivel connector 42 that snap-engages with the cylindrical portion 28 over resilient fingers 44. This embodiment obviates the need for a separate swivel connector elsewhere in the gas supply circuit.

In another embodiment (not shown) the swivel connection 42 is used in conjunction with the unitary housing 40.

Fig. 8 illustrates a further embodiment of the valve 14 incorporated into a mask 46 having a mask shell 48 and a mask cushion 50. In this embodiment, the valve 14 is integrally formed with the mask shell 48 thereby obviating the push-on connection between the mask 16 and the valve 14.

Fig. 9 shows an embodiment of the flap means 32 which includes an external rim 52 of stepped cross section which assists in locating the flap means 32 in the housing(s). The rim 54 is received within a corresponding recess in the housing to facilitate locating and mounting the flap means 32 in the housing.

Fig. 10 shows another embodiment of the flap means 32 having an internal rim 54 of rectangular cross section.

Fig's. 11 and 16 shows yet another embodiment of the flap means 32 having a substantially cylindrical formation 56 between the flaps 35 and the rim 52. The cylindrical formation 56 and the rim 52 facilitate locating the flap means 32 with correct orientation in the housing.

Fig. 12 illustrates a further embodiment of the flap means 32 which includes a series of pleats or folds 60 which flex to allow movement of the flap means 32 between the open and closed positions.

Fig. 13 shows another embodiment of the flap means 32 similar to that shown in Fig. 11 but without the slits 36. This embodiment thus has only a single flap 35 which distorts when moving between the open and closed positions.

Fig. 14 shows an embodiment similar to that of Fig. 13 but including three rows of perforations 58 which provide localised flexibility to assist in movement of the flaps 35 between the open and closed positions.

Fig. 15 shows an embodiment of a flap means 32 that has the cylindrical formation 56 of the embodiment of Fig's. 11 and 16 and the pleats or folds 60 of the embodiment of Fig. 12.

Figs. 17 and 18 show a further embodiment of a flap means 32 with a single flap 35 that includes a number of radial protuberances or ribs 62 of greater thickness than the flap 35. In the embodiment shown, the ribs 62 are of equal thickness. In other embodiments (not shown) the ribs are of unequal thickness and, for example, can be thicker on one side for operation in applications where flow is different across the flap means such as in a curved or angled conduit or the like.

Figs. 19 and 20 show examples of the cross-section the flap 35 can assume in the closed position.

Fig. 21 show an example of the cross-section the ribs 62 can assume in the open position.

Figs. 22 and 24 are schematic views of another embodiment of a flap means 32 that includes a one-way valve device 64 adapted to only allow gas flow in the direction of the patient. The one-way valve device 64 is known as a non-rebreathe valve.

Figs. 22 and 24 show the flap means 32 in the closed position and the one-way valve 64 in the open position, thereby allowing gas flow to the patient, as indicated by arrows 66. Fig. 23 shows the flap means 32 in the open position and the one-way valve 64 in the closed position, thereby directing all of the gas flow directed through the ports of the valve to atmosphere.

Another embodiment of the invention (not shown) includes a port or series of ports that function as both the flap assembly port(s) and the mask CO<sub>2</sub> gas washout port.

In this embodiment, the port(s) and the flap assembly are sized so the port(s) is/are not totally occluded by the flap assembly in the closed position. Accordingly, in the closed position the port(s) is/are occluded to an extent that it/they are of a size suitable to function as the mask CO<sub>2</sub> gas washout vent. When the pressure differential between the interior of the valve and atmosphere is below the operational threshold, the flap assembly moves to the open position and the port(s) to atmosphere is/are enlarged to a size suitable to function as the anti-asphyxia port(s).

The present invention has the advantage of being able to be used with nasal, mouth mask and full face (nose and mouth) mask systems for both adults and infants. In the situation of infants, the airflow is generally less, and thus the force needed to flex the flap assembly into the closed position is lowered accordingly.

The valve according to the present invention can be used for any type of air delivery system, it is preferably used in CPAP applications for the treatment of OSA or Non-Invasive Positive Pressure Ventilation (NIPPV).

Preferred embodiments of the valve of the present invention have the advantage of being able to operate independent of orientation. That is, although the valve has to be connected in the right direction between the flow generator and the

mask, it can be inverted, held sideways, etc. which often occurs during the time when the patient sleeps.

Another advantage of the valve of the present invention is it has only one moving or flexing part providing consistent operation.

- 5 Further, the valve can be disassembled, cleaned and reassembled very easily at home or at a hospital or clinic due to it having less parts.

The valve of the present invention is also very quiet in operation.

- Although the invention has been described with reference to specific examples, it will be appreciated by those skilled in the art that the invention may be embodied in  
10 many other forms. In particular, a valve of the present invention may be constructed of components which have dimensions, configurations and mechanical properties (including the mechanical properties of the flap assembly) that vary from those of the prototype. Such valves can have operating thresholds different from the prototype valve which achieved a closure at 2 cm H<sub>2</sub>O. The actual dimensions, configurations  
15 and mechanical properties will be chosen to achieve a valve having performance characteristic including operating threshold that will meet the specific needs of the chosen application.

## CLAIMS:

1. An anti-asphyxia valve adapted to, in use, be disposed between a patient and means to deliver a breathable gas to the patient, the valve comprising a housing having an interior, at least one port to provide fluid communication between the housing interior and atmosphere and a flap means comprising a first portion adapted for mounting to the housing and a second portion adapted to flex between a first biased open position allowing gas to pass from the housing interior through the port(s) to atmosphere when the difference in gas pressure in the housing interior and atmosphere is below a predetermined operating threshold and a second forced closed position substantially occluding the port(s) when the difference in gas pressure between the housing interior and atmosphere is substantially equal to or above the operating threshold.
2. The valve as claimed in claim 1, wherein the second portion completely occludes the ports in the closed position.
3. The valve as claimed in claim 1 or 2, wherein the housing includes a gas inlet in the form of a first substantially frusto-conical portion adapted to frictionally engage a flexible conduit in fluid communication with the means to deliver a breathable gas to the patient and a gas outlet in the form of a second substantially frusto-conical portion adapted to engage a mask or a flexible or rigid conduit in fluid communication with the mask.
4. The valve as claimed in claim 3, wherein the frusto-conical portions taper from a smaller distal end to a larger proximal end relative to the housing of the inlet valve.
5. The valve as claimed in claim 3 or 4, wherein one of the gas inlet or outlet includes a snap-engageable swivel portion adapted to engage the mask or flexible conduit.
6. The valve as claimed in any one of the preceding claims, wherein the housing is comprised of two housing parts which are releasably engageable with one another.
7. The valve as claimed in claim 6, wherein the housing parts engage by way of bayonet style fittings.
8. The valve as claimed in claim 6 or 7, when appended to claim 5, wherein the inlet and outlet are respectively provided on one of the two housing parts.
9. The valve as claimed in any one of claims 1 to 5, wherein the housing is of unitary construction.
10. The valve as claimed in any one of the preceding claims, wherein the housing includes a plurality of ports spaced about the periphery thereof and the second portion of the flap means of the flap means includes a like plurality of flaps.

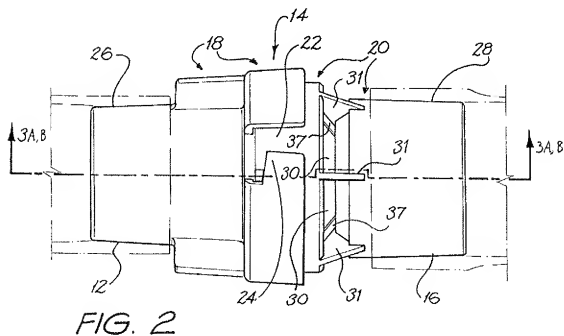
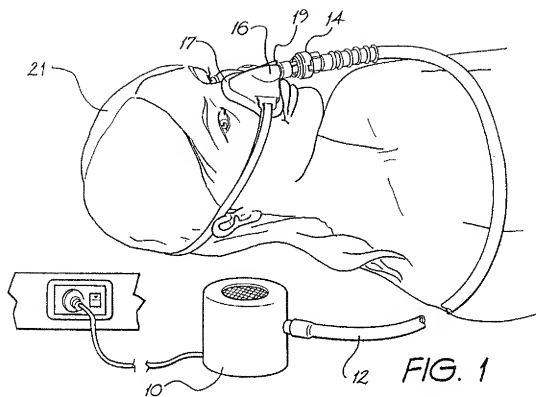
11. The valve as claimed in claim 10, wherein the housing includes three pairs of ports and the second portion of the flap means includes three flaps each adapted to close adjacent pairs of the ports.
12. The valve as claimed in any one of claims 1 to 9, wherein the second  
5 portion of the flap means is a single flap which is adapted to occlude all the port(s) in the second position.
13. The valve as claimed in claim 12, wherein the single flap includes perforations, ribs, pleats or folds or the like.
14. The valve as claimed in any one of the preceding claims, wherein the  
10 first and second portions are integrally formed.
15. The valve as claimed in any one of claims 1 to 13, wherein the first and second portions are initially formed from separate components that are later attached to each other.
16. The valve as claimed in any one of the preceding claims, wherein the  
15 first portion includes a rim adapted to assist in mounting the flap means to the housing.
17. The valve as claimed in claim 16, wherein the rim is an external rim of rectangular cross section which is adapted to engage an internal recess of substantially like cross-section in the housing.
18. The valve as claimed in claim 16 or 17, wherein the first portion  
20 includes a substantially cylindrical portion between the rim and the second portion.
19. The valve as claimed in claim 18, wherein the rim and/or the substantially cylindrical portion are tapered.
20. The valve as claimed in any one of the preceding claims, wherein the second portion of the flap means preferably terminates in an internal orifice.
21. The valve as claimed in claim 20, wherein the orifice includes a one-  
25 way valve adapted to only allow gas flow through the orifice in a direction towards the patient.
22. The valve as claimed in any one of the preceding claims, wherein the flap means is substantially round in cross-section.
23. The valve as claimed in any one of claims 1 to 21, wherein the cross  
30 section of the flap means is full or part elliptical or rectangular or other out-of-round shapes.
24. The valve as claimed in any one of the preceding claims, wherein the housing is manufactured from plastics material.
25. The valve as claimed in claim 23, wherein the plastics material is  
35 polycarbonate.
26. The valve as claimed in any one of the preceding claims wherein the flap assembly is preferably manufactured from a flexible elastomeric material.

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27. The valve as claimed in claim 25, wherein the elastomeric material is a silicone rubber.

28. The valve as claimed in any one of the preceding claims wherein the valve is integral with a mask.

5 29. The valve as claimed in any one of the preceding claims, wherein the operating threshold is about 2cm H<sub>2</sub>O.



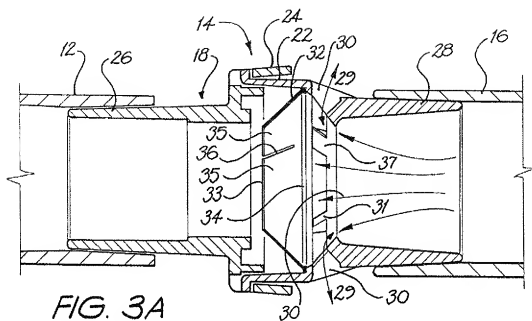


FIG. 3A

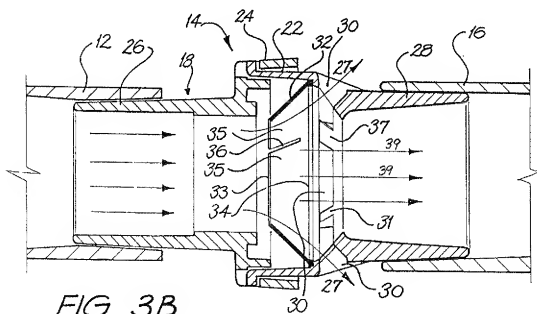


FIG. 3B



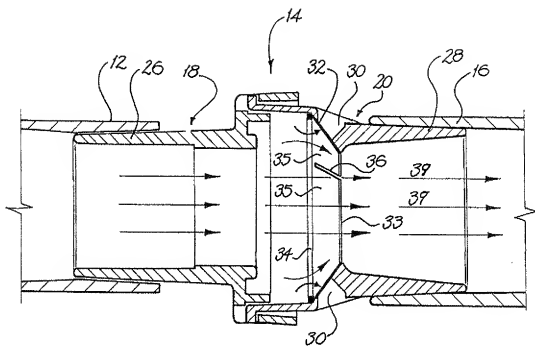


FIG. 4

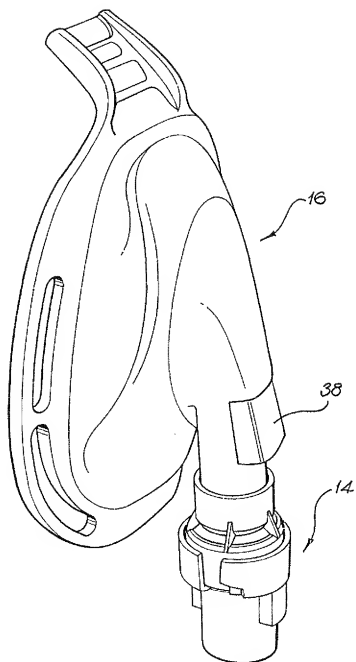
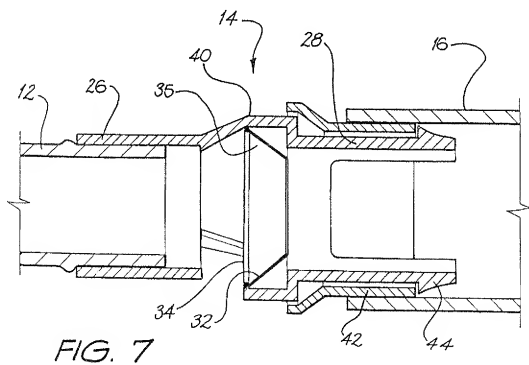
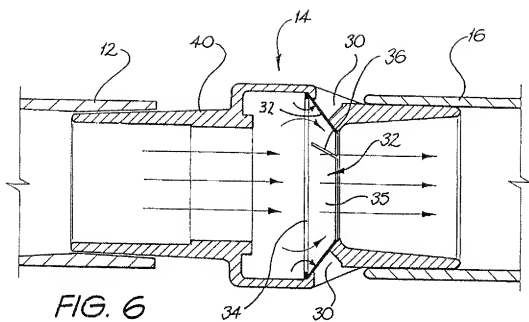


FIG. 5



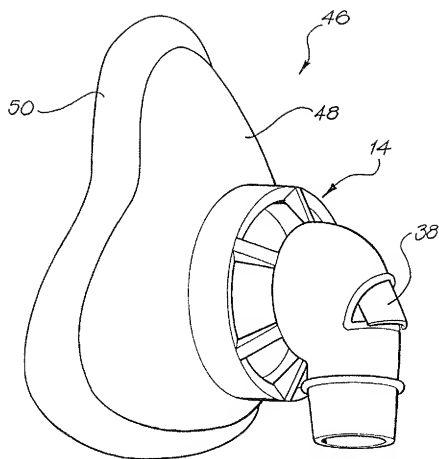


FIG. 8

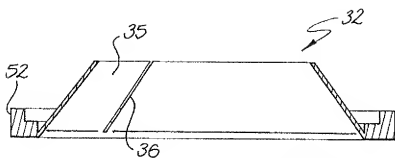


FIG. 9

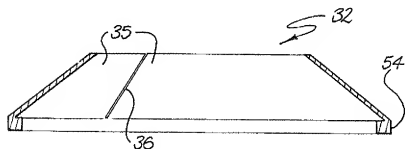


FIG. 10

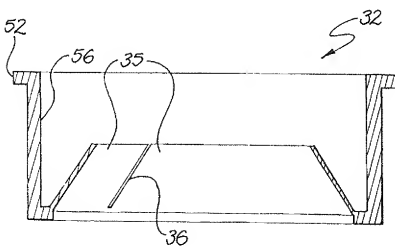


FIG. 11

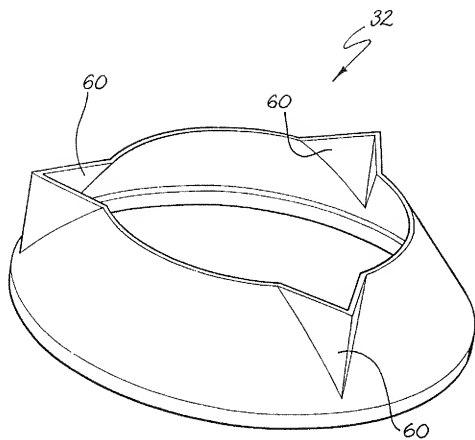


FIG. 12

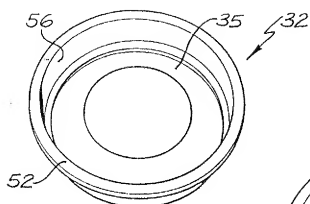


FIG. 13

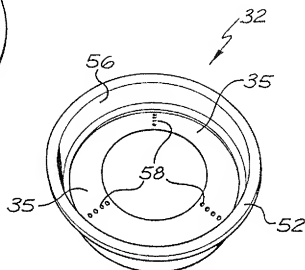


FIG. 14

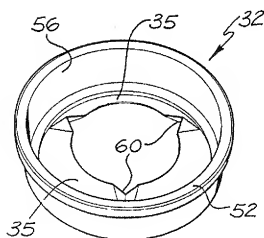


FIG. 15

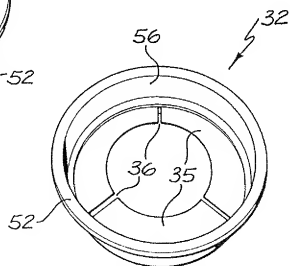
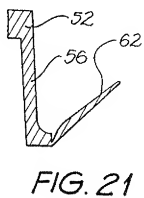
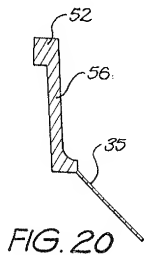
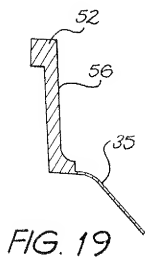
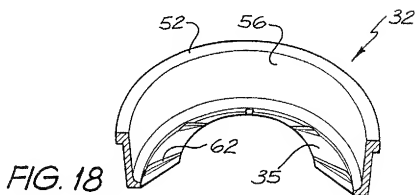
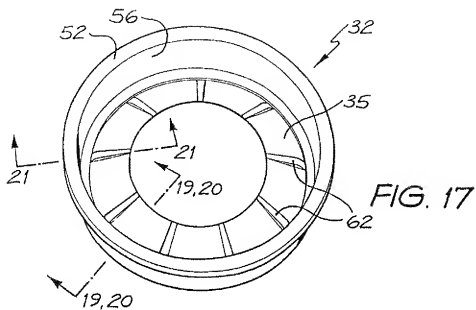


FIG. 16





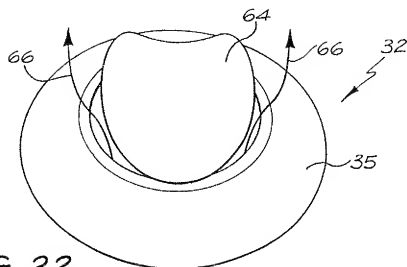


FIG. 22

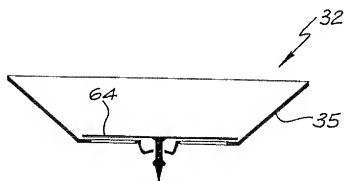


FIG. 23

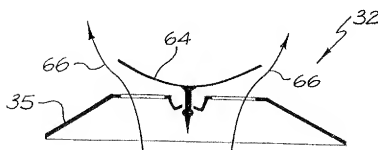


FIG. 24

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/01169

<b>A. CLASSIFICATION OF SUBJECT MATTER</b>		
Int Cl <sup>7</sup> : A61M 16/00		
According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b>		
Minimum documentation searched (classification system followed by classification symbols) A61M, F16K, A62B		
Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched		
Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI, JAPIO: valve, flap, shutter, disc, annul, respiration, breath, ventilate, vent, threshold		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 80/01645 A (HOVMAND) 21 August 1980 entire document	1,2,10,14,24-29
X	US 5398673 A (LAMBERT) 21 March 1995 column 2, lines 26-58; column 4, lines 16-60; column 5, line 42-column 6, line 15, figures 3, 4	1,2,6,7,9,12,14,15,22-29
X	WO 98/26830 A (RESMED LIMITED) 25 June 1998 entire document	1-29
<input checked="" type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
* Special categories of cited documents: "A" Document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family		
Date of the actual completion of the international search 23 February 2000		Date of mailing of the international search report - 7 MAR 2000
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200 WODEN ACT 2606 AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No.: (02) 6285 3929		Authorized officer  <b>MATTHEW FORWARD</b> Telephone No.: (02) 6283 2606

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU 99/01169

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 4870963 A (CARTER) 3 October 1989	

## INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.  
PCT/AU 99/01169

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
WO	80/01645	EP	24080	US	4226234		
US	5398673	NONE					
WO	98/26830	AU	48400/97	AU	53951/98	EP	968023
US	4870963	NONE					
END OF ANNEX							